

REMARKS

Claims 1, 3-5, 7-13, 15, 16, 18-22 and 66-85 are pending.

Restriction/Election

Claims 4, 8, 10 and 12 were indicated as withdrawn in the Office Action and the remaining claims were subjected to a restriction requirement.

Applicants thank the Examiner for discussing this application with applicants' undersigned attorney Laurie Butler Lawrence on August 9, 2007. As discussed, SEQ ID NOS: 12-15 and 107 are humanized 1D9 light chain variable regions and SEQ ID NO:98 is a nucleic acid sequence encoding a humanized 1D9 variable light chain. SEQ ID NOS:17-20 are humanized 1D9 heavy chain variable regions and SEQ ID NO:97 is a nucleic acid sequence encoding a humanized 1D9 heavy chain variable region. Upon filing of a request for continued examination (RCE), the Examiner agreed to proceed with examination of claims reciting SEQ ID NO: 98 and SEQ ID NOS:12-15 and 107, and SEQ ID NO: 97 and SEQ ID NOS: 17-20. The Examiner also required Applicants to select a light chain and heavy chain sequence from the sequences SEQ ID NOS:12-15 and SEQ ID NO:107 and SEQ ID NOS: 17-20, respectively, to facilitate the Office's search. Therefore, for searching purposes, Applicants elect the light chain sequence of SEQ ID NO: 12 and the heavy chain sequence of SEQ ID NO: 17. Applicants also herewith submit an RCE to continue prosecution of the present application.

New Matter Rejection

The Office Action further alleges:

Regarding claims 3, 7, 9, 11, the claims have been amended to cancel the originally elected invention, such as amino acid sequences SEQ ID NO:9 and 10 comprising the fragment of a light and heavy chain **variable** regions of the antibody, to recite new sequences, for the light chain variable region of SEQ ID NO: 12, 13, 14, 15, and 107, and for the heavy variable region SEQ ID NO: 17, 18, 19 and 20. ... The claims are currently rejected under 35 U.S.C. 112, first paragraph for new matter (see below) ... (Office Action- page 3; emphasis in original)

Applicants will respond to this rejection under the 112 rejections below.

35 U.S.C. § 112, Second Paragraph

Claims 1, 3, 5, 7, 9, 11, 13, 15, 16, 18, 19-22, and 66-85 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. According to the Office Action:

Claims 3, 7, 9, 11 have been amended to cancel amino acid sequences SEQ ID NO: 9 and 10 comprising the fragments of a light and heavy chain **variable** regions of the antibody, to recite new sequences: for the light chain variable region SEQ ID NO: 12, 13, 14, 15, or 107; and for the heavy variable region SEQ ID NO: 17, 18, 19, or 20. The specification (see page 31 and 32) defines SEQ ID NO: 12, 13, 14, 15, or 107 as sequences representing **constant light chain** regions of human origin, and SEQ ID NO: 17, 18, 19, or 20 representing **constant heavy chain** regions of human origin. ... It is unclear how the newly recited sequences are variable regions. Clarification and correction is required. (Office Action- pages 5-6; emphasis in original).

Applicants respectfully traverse the rejection for the following reasons.

The presently pending claims at issue in this rejection are generally drawn to a nucleic acid sequence encoding a humanized immunoglobulin light chain that include a variable region of SEQ ID NOs: 12, 13, 14, 15, or 107, a nucleic acid sequence encoding a heavy chain that includes the variable region of SEQ ID NOs: 17, 18, 19, or 20, and a humanized immunoglobulin or antigen binding fragment thereof that include combinations of the above. As stated at page 31, line 24, to page 32, line 32, of the Application as filed states:

... the light chain comprises at least 1 CDR of an antibody of non-human origin (e.g., 1D9) and framework and constant regions of human origin (e.g., SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 15, and SEQ ID NO: 107) ... the heavy chain comprises at least 1 CDR of an antibody of non-human origin (e.g., 1D9) and framework and constant regions of human origin (e.g., SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, and SEQ ID NO: 20).

In other words, SEQ ID NOs: 12-15 and 107 are disclosed above as comprising at least one CDR of an antibody of non-human origin. Likewise, SEQ ID NOs: 17-20 are disclosed above as comprising at least one CDR of an antibody of non-human origin. Applicants submit that one of skill in the art would recognize a CDR as a component of an antibody found

exclusively in the variable regions of the heavy and light chains of an antibody molecule. Thus, as SEQ ID NOs: 12-15 and 107 and 17-20 must comprise at least one CDR, one of skill in the art would understand that SEQ ID NOs: 12-15 and 107 and 17-20 are sequences that represent an antibody variable region. Furthermore, Figure 11 shows alignments of SEQ ID NOs: 12-15 (which according to the description at page 15, lines 8-16, of the application as filed, are designated 1D9RK<sub>A</sub> V<sub>K</sub>, 1D9RK<sub>B</sub> V<sub>K</sub>, 1D9RK<sub>C</sub> V<sub>K</sub>, and 1D9RK<sub>D</sub> V<sub>K</sub>, respectively) with 1D9 V<sub>K</sub>. Note, SEQ ID NOs: 12-15 each contain three fully conserved 1D9 V<sub>K</sub> CDRs. Figure 12 shows alignments of SEQ ID NOs: 17-20 (which according to the description at page 15, lines 17-26, of the application as filed, are designated 1D9RH<sub>A</sub> V<sub>H</sub>, 1D9RH<sub>B</sub> V<sub>H</sub>, 1D9RH<sub>C</sub> V<sub>H</sub>, and 1D9RH<sub>D</sub> V<sub>H</sub>, respectively) with 1D9 V<sub>H</sub>. Note, SEQ ID NOs: 17-20 each contain three highly conserved 1D9 V<sub>H</sub> CDRs. The labels "V<sub>K</sub>" and "V<sub>H</sub>" are well known in the art to identify a variable light chain and a variable heavy chain, respectively. Thus, it is clear from the present application that SEQ ID NOs: 12-15 and 107 are variable light chain sequences and SEQ ID NOs: 17-20 are variable heavy chain sequences.

Applicants respectfully submit, therefore, that claims 3, 7, 9, 11, 67-79, and 82-85, which recite one or more of SEQ ID NOs: 12-17, 107, and 17-20, or depend from a claim that recites one or more of SEQ ID NOs: 12-17, 107, and 17-20 are clear and definite in accordance with 35 U.S.C. § 112, second paragraph. Claims 1, 5, 13, 15, 16, 18, 19-22, 66, 80, and 81 do not recite SEQ ID NOs: 12-17, 107, and 17-20 and should not be subject to this rejection.

In view of the foregoing, Applicants request that the Office reconsider and withdraw the rejection of claims 1, 3, 5, 7, 9, 11, 13, 15, 16, 18, 19-22, and 66-85 under 35 U.S.C. § 122, second paragraph.

35 U.S.C. § 112, First Paragraph

Claims 1, 3, 5, 7, 9, 11, 13, 15, 16, 18, 19-22, and 66-85 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. In particular, the Office Action alleges (at pages 6-7)

... The claims are rejected because the specification does not describe SEQ ID NO: 12, 13, 14, 15, 107, or SEQ ID NO: 17, 18, 19, and 20 as representing variable regions as claimed in claims 3, 7, 9, and 11. Thus the variable regions comprising SEQ ID NO: 12, 13, 14, 15, or 107 and SEQ ID NO: 17, 18, 19, or 20 are considered to be new matter.

In response, Applicants resubmit the above remarks with regard to the variable regions of SEQ ID NOs: 12-17, 107, and 17-20. In light of these remarks, Applicants respectfully submit that one of skill in the art would understand that SEQ ID NOs: 12-17, 107, and 17-20 are described in the specification as sequences representing light and heavy chain variable regions, and as such are not new matter. Applicants respectfully request that the Office reconsider and withdraw the rejection of claims 1, 3, 5, 7, 9, 11, 13, 15, 16, 18, 19-22, and 66-85 under 35 U.S.C. § 112, first paragraph.

Applicant : LaRosa et al.  
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In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is requested to call the undersigned at (617) 521-7814.

The petition for the Extension of Time fee is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 10448-218002.

Respectfully submitted,

Date: 8/13/07

  
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